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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,097	08/23/2001	Michael Hershfield	1579-527	7948

23117 7590 10/24/2003
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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,097

Applicant(s)

HERSHFIELD ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/15/03, 6/16/03, 5/22/03 and 5/27/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 2, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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In accordance with the Decision On Petition mailed 9/10/03, the examiner will examine claims 2-5 and 16-17. Claims 6-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Papers No. 7 and 16.

The requirement is deemed proper and is therefore made FINAL.

The previous 25 USC § 112 second paragraph rejection of claims 16-17 is dropped in view of applicants arguments that the specification teaches that "non-deleterious PEG attachment sites in a uricase protein" "refer to attachment sites to a uricase protein which do not negatively impact the circulating life or reduce immunogenicity of the uricase proteins for safe and reliable use of chronic therapy". Therefore, the instant claims are limited to these characterizations that are in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 2, 4 and 8-11, does not reasonably provide enablement for the breadth of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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After reading applicants Remarks with the instant amendment, it was decided that the specification teaches that SEQ ID NO: 2, 4 and 8-11 retain significant uricase activity and have decreased antigenicity. However, the instant claims do not have any of the limitations of these embodiments. Claim 2 simply requires that the recombinant protein have one or more lysine residue inserted and that the protein be a chimeric protein with no limitations whatsoever as to what that protein is. Claims 16-17 simply require that the uricase have a lysine introduced. The instant specification does not teach one of ordinary skill in the art how to make the invention of the instant claims as it gives no guidance beyond the six sequences as to what embodiments will be operable. The previously cited passage on page 11, lines 12-19 indicate that this changes to uricase to add lysine residues was not predictable and therefore, the instant claims should be limited to the embodiments taught by the specification to have the desired characteristics.

The previous art rejections are being dropped because the Mura, et al. reference discloses inserting a lysine residue for reasons other than those anticipated by the inventors and the protein is not a chimeric one. The 35 USC § 103 rejection is being dropped because, although the cited references could have been used to make an obviousness rejection over at least claims 16-17 and possibly claim 2, as pointed out by applicants' Remarks, the specification teaches on page 11, lines 12-19 that "previous attempts to introduce attachment site by site-directed mutagenesis...were unsuccessful". Therefore the results were unexpected.

Applicants note that references labeled on the PTO-1449 have been crossed out but opine that they believe that the examiner has considered

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these references and that the Notice Of Acceptance dated 10/11/01 indicates that these references had been received. The examiner had not considered these references and that was indicated by the references being crossed out. Furthermore, in most cases the references submitted with a search report are not included with the U.S. 371 application. In order to try and move the prosecution of this application forward the examiner has attempted to locate these references, taking significant time on his part, and they are indicated on the attached PTO-892. It is noted that with the Hershfield reference cited previously on the PTO-892 filed with the previous action, all of the references listed on the 2/2/01 PTO-1449 have been listed except the Wu, et al. reference in J. Mol. Evol. This reference is not available in the PTO and if applicants wish this reference considered they should submit it.

Claim 5 is allowed. Claims 3 and 4 are objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 22, 2003